July 29, 2002

Mr. Lynne R. Harris
Executive Director
The Society of the Plastics Industry, Inc.
Epoxy Resin Systems Task Group
1801 K. Street, N.W.
Suite 600K
Washington, DC 20006-1301

Dear Mr. Harris:

The Office of Pollution and Toxics is transmitting EPA's comments on the robust summaries and test plan for Alkyl (C-12-C14) Glycidyl Ether, posted on the ChemRTK HPV Challenge Program Web site on January 14, 2002. I commend The Epoxy Resin Systems Task Group for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed Comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that The Epoxy Resin Systems Task Group advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site "Submit Technical Questions" button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Alkyl (C_{12}-C_{14}) Glycidyl Ether

SUMMARY OF EPA COMMENTS

The Sponsor, the Society of the Plastics Industry, Inc., submitted a test plan and robust summaries to EPA for alkyl (C_{12}-C_{14}) glycidyl ether (CAS No. 68609-97-2) dated December 7, 2001. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 14, 2002.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical and Environmental Fate Endpoints. The submitter needs to provide robust summaries for all physicochemical endpoints. Some input values for the fugacity model in the robust summary differ from those provided in the test plan.

2. Health Endpoints. All appropriate SIDS-level endpoints have been addressed. However, the submitter needs to address deficiencies in the robust summaries.

3. Ecotoxicity. EPA agrees with the submitter's plan to conduct testing for the fish, invertebrate, and algal endpoints.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA COMMENTS ON THE ALKYL (C_{12}-C_{14}) GLYCIDYL ETHER CHALLENGE SUBMISSION

Test Plan

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

The test plan for melting point, boiling point, vapor pressure, and partition coefficient endpoints is adequate for the purposes of the HPV Challenge Program. However, the submitter needs to provide robust summaries for all physicochemical endpoints. It is not sufficient to provide these data solely in the test plan.

Water Solubility. The submitter needs to provide measured data for this endpoint. The use of estimated values introduces uncertainties that then become magnified in modeling applications.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity).

The test plan for these endpoints is adequate for the purposes of the HPV Challenge Program. Measured data are especially important for the stability in water and ready biodegradability endpoints.

Health Effects (acute toxicity, repeat dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

Adequate data are available for repeated-dose, genetic, and developmental toxicity endpoints for the purposes of the HPV Challenge Program. However, the submitter needs to address some deficiencies in the robust summaries.

Acute Toxicity. One oral acute study in rats and one dermal acute study in rabbits were submitted. While

neither study is adequate, no further testing is needed for this endpoint because no mortality was reported for the dermal study during the 3-day observation period at the highest dose level of 4.5 ml/kg (approximately 4000 mg/kg body weight), which is greater than the limit dose level of 2000 mg/kg established by the OECD guidelines.

Reproductive Toxicity. Data are available for a 13-week repeated-dose dermal study in rats for which reproductive organs were examined histopathologically, and no adverse effects were observed. This study together with the adequate developmental toxicity study is considered adequate for the reproductive toxicity endpoint.

Ecotoxicity.

EPA agrees with the submitter's proposal to conduct testing for acute toxicity to fish, invertebrates, and algae.

Specific Comments on the Robust Summaries

Environmental Fate.

Fugacity. The vapor pressure data (0.00105 mm Hg) and melting point data (57.9 deg C) used as inputs in the fugacity model in the robust summary differ from those values provided on page 2 of the test plan (vapor pressure: 0.06 mm Hg @ 70 °C; and melting point: 35 °C). The submitter needs to reconcile these differences. The submitter needs to use measured data as inputs into the fugacity model or justify the alternative. The use of estimated values, as in this case, introduces uncertainties that then become magnified in modeling applications.

Health Effects.

Repeated-dose Toxicity. No quantitative data are presented. It is not stated whether collars were used and whether the animals were housed individually to prevent grooming and consequent ingestion of the test substance.

Developmental Toxicity. No quantitative data are presented.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.